

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

GENBIOPRO, INC.,

Plaintiff,

v.

**MARK A. SORSAIA, in his official capacity
as Prosecuting Attorney of Putnam County
AND PATRICK MORRISEY, in his official
capacity as Attorney General of West Virginia,
*Defendants.***

**Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)**

**PLAINTIFF'S OPPOSITION TO DEFENDANT MARK A. SORSAIA'S
MOTION TO DISMISS**

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INTRODUCTION AND BACKGROUND

GenBioPro is one of two companies in the United States licensed to sell mifepristone, a medication the U.S. Food and Drug Administration (“FDA”) approved and indicated for use in medication abortion. Medication abortion, which FDA approved to terminate a pregnancy up to 70 days’ gestation, has grown as a share of overall elective abortions in recent years. Unlike procedural abortion (sometimes referred to as “surgical abortion”), medication abortion allows patients to terminate a pregnancy at home and provides other important clinical and care benefits. Medication abortion is safe, but mifepristone is contraindicated for certain patients, such those with an ectopic pregnancy.

Congress enacted the Food and Drug Administration Amendments Act of 2007 (“FDAAA”), Pub. L. No. 110-85, 121 Stat. 823, authorizing FDA to regulate the distribution, prescribing, and disposal — not just approval — of certain drugs under a Risk Evaluation and Mitigation Strategy (“REMS”). *See* 21 U.S.C. § 355-1(a). Congress specified that the 16 drugs previously approved with “elements to assure safe use,” including mifepristone, would be “deemed to have in effect an approved [REMS]” upon the Act’s passage. FDAAA § 909(b)(1), 121 Stat. 950-51, *reprinted at* 21 U.S.C. § 331 note.¹ Congress required that any elements to assure safe use “[p]rovid[e] safe access for patients” to the drugs in question. *Id.* § 505-1(f), 121 Stat. 926, 930 (codified at 21 U.S.C. § 355-1(f)). It further mandated that any restrictions on the drug, such as limits on how it can be prescribed or dispensed, “not be unduly burdensome on patient access to the drug” and required that the restrictions “minimize the burden on the health care delivery system.” *Id.* § 505-1(f)(2)(C)-(D), 121 Stat. 930 (codified at 21 U.S.C. § 355-

¹ All references to “mifepristone” are to Mifepristone Tablets, 200 mg.

1(f)(2)(C)-(D)). These provisions reflect a congressional mandate that FDA strike a balance between safety and patient access.

Since Congress enacted the FDAAA, FDA has continued to regulate mifepristone subject to a REMS with elements to assure safe use. The most recent mifepristone REMS FDA issued in 2023 requires healthcare providers to become specially certified by mifepristone’s manufacturers to prescribe mifepristone, and to agree to follow certain guidelines in prescribing the drug to patients. U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg* at 1 (Jan. 2023) (“2023 REMS Document”), https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_REMS_Full.pdf. The REMS also requires pharmacies dispensing mifepristone to become specially certified and agree to comply with several restrictions on dispensing. *Id.* at 2-3.

Contravening Congress’s mandate, West Virginia enacted the Unborn Child Protection Act (the “Criminal Abortion Ban” or the “Ban”)² to ban abortion, including medication abortion, in almost all circumstances for which mifepristone is indicated. The Ban imposes burdens on access to the drug and on the healthcare delivery system, including criminal penalties. The Ban is preempted because it conflicts with the congressionally mandated determination by FDA to ensure safe access to the drug. GenBioPro sued Defendant Mark A. Sorsaia, the state prosecutor charged with enforcing the Ban in Putnam County, where the statute constricts GenBioPro’s pool of buyers. GenBioPro seeks, *inter alia*, a declaration that the Ban is preempted and violates the Commerce Clause, and an order enjoining Sorsaia from enforcing it.

² The Criminal Abortion Ban refers to West Virginia Code §§ 16-2R-1 *et seq.* and 61-2-8. The State’s “Restrictions” on abortion refer to West Virginia Code §§ 16-2I-2 (requiring a waiting period and counseling before an abortion procedure), 30-3-13a(g)(5) (prohibiting providers from prescribing mifepristone via telemedicine), and 30-1-26(b)(9) (providing for a rule banning prescribing mifepristone via telemedicine).

Sorsaia’s motion focuses on whether he is a proper defendant, couching the argument in terms of GenBioPro’s standing to sue him and the plausibility of its claims against him. His arguments fail because, as a state official charged with enforcing the Ban (and all violations of the criminal code in Putman County), Sorsaia is the proper target of an action to enjoin the Ban. Indeed, Sorsaia publicly announced his intention to enforce the State’s abortion law.

GenBioPro’s injuries, which include economic harm and the threat of enforcement, are traceable to Sorsaia for the same reason: he is responsible for enforcing the statute and has indicated his intent to do so. If this Court enjoins him from enforcing the Ban, providers eligible to prescribe mifepristone and pharmacies certified to provide it could do so in Putnam County, redressing GenBioPro’s injury by enabling it to sell its product. *See Uzuegbunam v. Preczewski*, 141 S. Ct. 792, 801 (2021) (“[T]he ability ‘to effectuate a partial remedy’ satisfies the redressability requirement.”).

STANDARD OF REVIEW

When a defendant challenges a plaintiff’s standing at the motion-to-dismiss stage for failing to “allege facts upon which standing can be based,” under Federal Rule of Civil Procedure 12(b)(1), as Sorsaia does, the “plaintiff is afforded the same procedural protection that exists on a motion to dismiss.” *Wikimedia Found. v. Nat’l Sec. Agency*, 857 F.3d 193, 208 (4th Cir. 2017) (brackets and internal quotation marks omitted). The Court “accept[s] as true all well-pleaded facts in [the] complaint and construe[s] them in the light most favorable to the plaintiff.” *Id.*; *see Tyree v. United States*, 814 F. App’x 762, 766 (4th Cir. 2020) (per curiam).

A Rule 12(b)(6) motion tests the legal sufficiency of a complaint. *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008). A complaint need only contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2).

This standard “does not require ‘detailed factual allegations.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The court views the “well-pled facts . . . in the light most favorable to the plaintiff.” *Brockington v. Boykins*, 637 F.3d 503, 505 (4th Cir. 2011). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678.

ARGUMENT

I. GENBIOPRO HAS STANDING TO SEEK RELIEF AGAINST SORSAIA, WHO IS CHARGED WITH AND HAS CREDIBLY THREATENED ENFORCEMENT

GenBioPro has individual and third-party standing. To establish standing, “a plaintiff must show (1) an ‘injury in fact,’ (2) a sufficient ‘causal connection between the injury and the conduct complained of,’ and (3) a ‘likel[i]hood’ that the injury ‘will be redressed by a favorable decision.’” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157-58 (2014) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992)).

A. GenBioPro Suffered An Injury In Fact

The requirement of a “concrete and particularized” injury in fact “helps to ensure that the plaintiff has a ‘personal stake in the outcome of the controversy.’” *Id.* at 158 (quoting *Warth v. Seldin*, 422 U.S. 490, 498 (1975)). GenBioPro meets this requirement for two reasons, each of which independently supports standing. First, GenBioPro suffered an economic injury: lost sales and constriction of its market across the State, including in Putnam County. Second, Sorsaia credibly threatened to enforce the Ban.

1. GenBioPro’s Financial Injury

“[F]inancial harm is a classic and paradigmatic form of injury in fact.” *Md. Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 210 (4th Cir. 2020) (quoting *Air Evac EMS, Inc. v. Cheatham*, 910

F.3d 751, 760 (4th Cir. 2018)). In *Maryland Shall Issue*, a firearms dealer (among others) sued to enjoin Maryland’s handgun licensing law, which prevented the store from selling guns to customers without a handgun license. The Fourth Circuit found that the store had an economic injury in the form of “lost business opportunities.” *Id.* at 211 (citing *Craig v. Boren*, 429 U.S. 190, 194 (1976)). It held that “the operation of a challenged statute that results in the constriction of a vendor’s buyers’ market plainly inflicts an injury in fact sufficient to guarantee it concrete adverseness.” *Id.* (alterations and internal quotation marks omitted) (citing *Craig*, 429 U.S. at 194); *see also Ezell v. City of Chicago*, 651 F.3d 684, 696 (7th Cir. 2011) (“[S]upplier of firing-range facilities is harmed by the firing-range ban.”).

GenBioPro’s economic injury meets this test. GenBioPro alleges that West Virginia’s Ban “severely constricted the market for mifepristone statewide,” Compl. ¶ 11, and that its Restrictions on abortion “restricted the provision of mifepristone.” *Id.* ¶ 12. GenBioPro’s sales of generic mifepristone and its companion drug in the FDA-approved regimen for medication abortion are its sole source of revenue. *Id.* ¶ 23. GenBioPro alleges that “West Virginia’s severe abortion Restrictions and Criminal Abortion Ban make it impossible for GenBioPro to promote and market its product in West Virginia as it does in other [S]tates.” *Id.* ¶ 77. By contrast, nationally, the market for mifepristone is strong and sales have grown over time, even as the total number of abortions has declined. *Id.* ¶ 76.

The constriction of GenBioPro’s “buyers’ market,” extends throughout West Virginia. *Md. Shall Issue*, 971 F.3d at 211. Walgreens, which operates stores in Putnam County and stated publicly in January that it intended to sell mifepristone, Compl. ¶ 78, reversed course after West Virginia and other States threatened legal action if Walgreens began distributing mifepristone. *See Alice Miranda Ollstein, Walgreens Won’t Distribute Abortion Pills in States Where GOP*

AGs Object, Politico (Mar. 2, 2023), <https://www.politico.com/news/2023/03/02/walgreens-abortion-pills-00085325>; *see also* Letter from Att’y Gen., to Danielle Gray, Exec. Vice President, Walgreens Boots All., Inc. (Feb. 1, 2023), https://ago.mo.gov/docs/default-source/press-releases/2023-02-01-fda-rule---walgreens-letter-danielle-gray.pdf?sfvrsn=ff1e6652_2. GenBioPro would be able to provide mifepristone to more patients, including in Putnam County, if the Ban did not prevent such sales. Compl. ¶ 78. GenBioPro likewise alleges that the Ban prevents HoneyBee Health, which ships prescription drugs nationwide, and CVS from providing mifepristone to patients in West Virginia, including in Putnam County. *Id.* The Ban and Restrictions thereby “cause[] significant, ongoing economic injury to GenBioPro in the form of lost sales, customers, and revenue.” *Id.* ¶ 79. These allegations state an injury in fact. *See Md. Shall Issue*, 971 F.3d at 212 (“[A] loss of even a small amount of money is ordinarily an ‘injury.’”) (quoting *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017)).

2. GenBioPro Suffers A Credible Threat Of Future Enforcement

Even if GenBioPro did not allege economic harm, it would still have a concrete injury because it “alleges ‘an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.’” *Susan B. Anthony*, 573 U.S. at 159 (quoting *Babbitt v. United Farm Workers Nat’l Union*, 442 U.S. 289, 298 (1979)).

GenBioPro alleges its intent “to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute.” *Id.* It seeks to “promote and market its product in West Virginia as it does in other states.” Compl. ¶ 77. GenBioPro intends to certify healthcare providers in West Virginia to prescribe mifepristone and certify pharmacies to dispense mifepristone in West Virginia as required by the 2023 mifepristone REMS. *See Id.* ¶¶ 66-67, 77-78, 80; *see also* 2023 REMS Document at 1. But for the Ban, these providers and

pharmacies would prescribe and dispense GenBioPro's product. The Ban "severely constricts GenBioPro's pool of potential customers," including healthcare providers and certified pharmacies that would purchase mifepristone distributed by GenBioPro, and impermissibly constrains GenBioPro's ability to market its product in West Virginia. Compl. ¶ 79. "Providing mifepristone through" CVS, Walgreens, and other pharmacies located in Putnam County and through mail-order pharmacies that would dispense drugs to patients residing in Putnam County in the absence of the laws being challenged "would enable GenBioPro to serve more patients with its product" by selling mifepristone to them. *Id.* ¶ 78.

GenBioPro's intended course of conduct is "affected with a constitutional interest" and "proscribed by a statute." *Susan B. Anthony*, 573 U.S. at 159. The Ban violates the Supremacy Clause, because it conflicts with Congress's determination that mifepristone should be subject to a REMS, 21 U.S.C. § 355-1. Compl. ¶¶ 94-99. The Ban violates the Commerce Clause by impeding the free flow of trade in the national common market and creating an undue burden on access to mifepristone, an article of commerce subject to national uniform regulation. *Id.* ¶¶ 103-104, 106-109.

Moreover, "the threat of future enforcement of the [challenged] statute is substantial." *Susan B. Anthony*, 573 U.S. at 164. Sorsaia stated publicly that, "[a]s prosecutors we have a clear obligation to enforce the laws of our state. I believe if abortion is illegal then no responsible medical provider will be doing them." Compl. ¶ 24 & n.7. There is no reason to doubt Sorsaia's intention to enforce the new Ban. *See Virginia v. Am. Booksellers Ass'n, Inc.*, 484 U.S. 383, 393 (1988) ("We are not troubled by the pre-enforcement nature of this suit. The State has not suggested that the newly enacted law will not be enforced, and we see no reason to assume otherwise. We conclude that plaintiffs have alleged an actual and well-founded fear that

the law will be enforced against them.”); *Mobil Oil Corp. v. Att’y Gen. of Va.*, 940 F.2d 73, 76 (4th Cir. 1991) (“In the instant case, the amendment is newly enacted. It would be unreasonable to assume that the General Assembly adopted the . . . amendment without intending that it be enforced.”). Indeed, at least one pharmacy through which GenBioPro seeks to provide mifepristone, Walgreens, *see* Compl. ¶ 78, has taken seriously the threat of enforcement of West Virginia’s ban, and has publicly reversed course on its intent to offer the product in certain States in response to threatened enforcement. *See supra* pp. 5-6.

Nor did Sorsaia “disavow[] enforcement” of the Ban. *Susan B. Anthony*, 573 U.S. at 165; *see also Holder v. Humanitarian L. Project*, 561 U.S. 1, 15 (2010) (claims justiciable where government had declined to disavow future prosecution); *303 Creative LLC v. Elenis*, 6 F.4th 1160, 1174, 1188 (10th Cir. 2021) (“Colorado declines to disavow future enforcement” of law prohibiting statements “indicating that an individual’s patronage or presence at a . . . public accommodation [wa]s unwelcome . . . because of [protected status].”), *cert. granted on other grounds*, 142 S. Ct. 1106 (2022) (internal quotation marks omitted); *cf. Md. Shall Issue*, 971 F.3d at 218 (individuals lacked standing where State disavowed, and had not threatened, enforcement).

B. GenBioPro’s Injuries Are Fairly Traceable To Sorsaia

An injury is traceable if “‘there [is] a causal connection between the injury and the conduct complained of’ by the plaintiff.” *Md. Shall Issue*, 971 F.3d at 212 (quoting *Lujan*, 504 U.S. at 560). “[T]he question is whether [the plaintiff] can demonstrate that the [challenged statute] is ‘fairly traceable’ to its injury, though it does not have to be ‘the sole or even immediate cause of th[at] injury.’” *Id.* (quoting *Sierra Club v. U.S. Dep’t of Interior*, 899 F.3d 260, 283-84 (4th Cir. 2018)); *see Libertarian Party v. Judd*, 718 F.3d 308, 316 (4th Cir. 2013) (causation satisfied when challenged requirement “is at least in part responsible for frustrating”

plaintiff's rights). "Traceability" requires the Court to consider "the effect of the state's chosen course of action . . . as an integrated whole." *Air Evac*, 910 F.3d at 760.

That requirement is met here. West Virginia's Ban, on its face, undoubtedly constrains GenBioPro's ability to sell and promote its product for purchase and use throughout West Virginia and limits its potential customer base. *See* Compl. ¶¶ 77-79. Those allegations suffice under *Maryland Shall Issue*, where the licensing requirement for handgun sales "[o]n its face . . . undoubtedly constrain[ed] [the plaintiff's] ability to sell handguns and limit[ed] its potential customer base." 971 F.3d at 212. GenBioPro alleges it "lost sales, customers, and revenue" as a result of the statute. Compl. ¶ 79. "[W]hen a 'challenged provision[] . . . inhibits [a vendor's] ability to' conduct its business, 'the alleged injury is . . . traceable to the' provision at issue." *Md. Shall Issue*, 971 F.3d at 213 (alterations in original) (quoting *Air Evac*, 910 F.3d at 760); *see also Primera Iglesia Bautista Hispana of Boca Raton, Inc. v. Broward Cnty.*, 450 F.3d 1295, 1304 (11th Cir. 2006) (traceability satisfied when challenged law "directly and expressly limits" the plaintiff's conduct).

An injury caused by a statute is fairly traceable to a state official charged with enforcing the statute: here, Sorsaia. *See Mobil Oil*, 940 F.2d at 76 (standing exists where official "has not . . . disclaimed any intention of exercising h[is] enforcement authority"); *see also, e.g., Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 919-20 (9th Cir. 2004) (attorney general and county prosecutor are proper defendants when they have authority to enforce the challenged statute); *303 Creative LLC v. Elenis*, 2017 WL 4331065, at *4 (D. Colo. Sept. 1, 2017) ("An injury in fact is fairly traceable to a defendant if the defendant is charged with the responsibility to enforce the statute."). Section 7-4-1(a) of the West Virginia Code authorizes Sorsaia to "attend to the criminal business of the state in the county in which he . . . is elected

and qualified” and mandates that when Sorsaia “has information of the violation of any penal law committed within the county, . . . [he] shall institute and prosecute all necessary and proper proceedings against the offender.” *See also State ex rel. Games-Neely v. Sanders*, 641 S.E.2d 153, 162 (W. Va. 2006).

Sorsaia has acknowledged he is charged with enforcing West Virginia’s criminal laws, which include the abortion Ban. Compl. ¶ 24 (citing W. Va. Code § 7-4-1(a)); *see id.* ¶ 24 & n.7 (quoting Sorsaia’s view of his “clear obligation” as a “prosecutor[.]” to exercise his enforcement powers); *see also State ex rel. Preissler v. Dostert*, 260 S.E.2d 279, 287 (W. Va. 1979) (“[T]he prosecuting attorney is elected by the people of the county to represent them in prosecutions against criminal offenders.”). In fact, he has told the press that he will enforce the State’s abortion law. *See supra* p. 7. Therefore, injury caused by the statute is fairly traceable to him.

C. A Declaration From This Court That The Ban Is Unconstitutional And Cannot Be Enforced Would Redress GenBioPro’s Injury

“A claim is redressable if a favorable outcome would repeal the ‘burdens’ on purchasing the plaintiff’s goods.” *Md. Shall Issue*, 971 F.3d at 213. In *Maryland Shall Issue*, the court held that the vendor’s “asserted injury [wa]s redressable because the injunctive relief sought . . . would allow it to sell handguns to a broader range of potential customers, thereby increasing its opportunity to make sales and generate revenue.” *Id.* at 214; *see Nat’l Rifle Ass’n v. Magaw*, 132 F.3d 272, 282 (6th Cir. 1997) (holding that a favorable ruling likely to redress an injury where plaintiff “abandoned a line of business because of passage of the [challenged law and] . . . would promptly resume the prohibited activities” if “the [law was] declared unconstitutional”). Similarly, GenBioPro’s injury is likely to be redressed by a favorable judicial decision finding West Virginia’s Ban unconstitutional on preemption or Commerce Clause grounds and enjoining its enforcement. Such a determination would permit GenBioPro to sell mifepristone “to a

broader range of potential customers, thereby increasing its opportunity to make sales and generate revenue.” *Md. Shall Issue*, 971 F.3d at 214.

The remedy sought against Sorsaia will enjoin the Ban’s criminal enforcement and redress GenBioPro’s injury. *See* Compl. at 32 (prayer for relief). The Ban subjects healthcare providers, including advanced practice registered nurses prescribing mifepristone and pharmacies dispensing the medication, to criminal prosecution, contrary to FDA’s REMS governing mifepristone. The Ban makes it a felony for certain providers who do not meet West Virginia’s definition of “licensed medical professional,” such as physician assistants and advanced practice registered nurses, to perform abortions. W. Va. Code § 16-2R-2 (defining “licensed medical professional” as “a person licensed under § 30-3-1 *et seq.*, or § 30-14-1 *et seq.*, of this code,” which does not include physician assistants licensed under Chapter 30, Article 3E, or advanced practice registered nurses licensed under Chapter 30, Article 7). Physician assistants and advanced practice registered nurses in West Virginia can prescribe drugs and diagnose patients,³ making them eligible to be certified to prescribe mifepristone under the 2023 REMS. Yet the Ban prevents them from doing so, further constricting the market for GenBioPro’s product. Similarly, the Ban provides criminal penalties for pharmacists who “knowingly . . . induce[.]” an abortion by dispensing mifepristone to a pregnant person not permitted to obtain an abortion under the Ban. *Id.* § 61-2-8.

³ W. Va. Code §§ 30-3E-1 (physician assistants may “practice medicine” alongside a collaborating physician), 30-3E-12 (physician assistants may “perform medical acts,” including “prescribing, dispensing, and administering . . . prescription drugs”), 30-7-1 (advanced practice registered nurses may provide “[d]irect patient care,” including “assessment, treatment, counseling, procedures, . . . administration of medication, and implementation of a care plan”), 30-7-15b(a) (advanced practice registered nurses may “prescribe drugs”).

Because of the Ban, major brick-and-mortar pharmacies (and HoneyBee Health, a mail-order pharmacy) that otherwise would sell mifepristone to patients in Putnam County will not, thereby constricting the market for GenBioPro's product. *See supra* pp. 5-6 (describing Walgreens's decision not to dispense mifepristone in States where it is banned). An order enjoining Sorsaia from enforcing the Ban would permit providers in Putnam County to prescribe their patients mifepristone, and would permit pharmacies to provide it pursuant to the REMS, redressing GenBioPro's economic injury. *Cf. W. Va. Citizens Def. League, Inc. v. City of Charleston*, 2012 WL 4320983, at *9 (S.D.W. Va. Sept. 20, 2012) (where an "injury is the fear of prosecution and essentially forced compliance with" an unlawful law, if that law is "declared unlawful the injury will be redressed").

D. GenBioPro Satisfies The Requirements For Third-Party Standing

GenBioPro's economic injury is sufficient to support its standing to sue. But, in the alternative, GenBioPro also satisfies the requirements for third-party standing. In assessing third-party standing, courts "determine 'whether the third party has sufficient injury-in-fact to satisfy the Art[icle] III case-or-controversy requirement' . . . 'and whether, as a prudential matter, the third party can reasonably be expected properly to frame the issues and present them with the necessary adversarial zeal.'" *Md. Shall Issue*, 971 F.3d at 214-15 (quoting *Sec'y of State of Md. v. Joseph H. Munson Co.*, 467 U.S. 947, 956 (1984)). Courts consider whether there is "'a close relation[ship]' with the person who possesses the right," and "a 'hindrance' to the possessor's ability to protect his own interests." *Id.* at 215 (quoting *Powers v. Ohio*, 499 U.S. 400, 411 (1991)).

As a vendor of mifepristone, GenBioPro has "third-party standing to pursue claims on behalf of its customers, regardless of whether [its] customers are hindered in bringing their own claims." *Id.* 216 (collecting cases). The Supreme Court "has unequivocally held that 'a vendor

with standing to challenge the lawfulness of’ a regulation — as [the plaintiff] has here — ‘is entitled to assert those concomitant rights of third parties that would be diluted or adversely affected should [its] constitutional challenge fail and the [regulations] remain in force.’” *Id.* at 215 (quoting *Craig*, 429 U.S. at 195). “Otherwise, the threatened imposition of governmental sanctions might deter a plaintiff and other similarly situated vendors from selling their items to members of their potential customer base, thereby ensuring that enforcement of the challenged restriction against the [vendor] would result indirectly in the violation of third parties’ rights.” *Id.* (internal quotation marks omitted).

GenBioPro satisfies this test. Its economic injury meets the injury-in-fact requirement of Article III. *See supra* pp. 4-8. And it has a close relationship with parties subject to enforcement of the Ban, particularly the healthcare providers and pharmacies that provide GenBioPro’s mifepristone to patients. GenBioPro must certify those providers and pharmacies under the REMS. GenBioPro also furnishes mifepristone to patients through healthcare providers, who are subject to penalties for providing mifepristone to patients in violation of the Ban. Compl. ¶¶ 71, 73, 79. This includes criminal penalties on certain healthcare providers eligible to prescribe mifepristone under the 2023 REMS. *See id.* ¶ 71 (discussing W. Va. Code §§ 16-2R-7, 61-2-8(a), 16-2R-2); *see supra* p. 11 (explaining that certain nurses are eligible to prescribe mifepristone under the REMS but forbidden from doing so by West Virginia law on pain of criminal penalties). Under the 2023 REMS, GenBioPro also may, and intends to, provide mifepristone to patients through pharmacies, which are likewise subject to enforcement under the Ban in conflict with the REMS. Compl. ¶ 78.

In similar circumstances, “vendors and those in like positions have been uniformly permitted to resist efforts at restricting their operations by acting as advocates of the rights of

third parties who seek access to their market or function.” *Md. Shall Issue*, 971 F.3d at 216 (quoting *Craig*, 429 U.S. at 195). “Courts have invariably found that a vendor has a sufficiently close relationship with its customers when a challenged statute prevents that entity from transacting business with them.” *Id.* (citing *Craig*, 429 U.S. at 192-97; *Lepelletier v. FDIC*, 164 F.3d 37, 43-44 (D.C. Cir. 1999)); *see Lepelletier*, 164 F.3d at 44 (holding that a close relationship can exist “on the basis of the vendor-vendee relationship alone”) (internal quotation marks omitted).

E. Sorsaia’s Standing Arguments Fail

In arguing that GenBioPro lacks standing, Sorsaia asserts that GenBioPro must demonstrate it will be harmed by Sorsaia’s actions in Putnam County more than it would be harmed by enforcement in the rest of the State for GenBioPro to have standing to sue him. No law supports that argument.

First, Sorsaia argues (at 3) that GenBioPro cannot sue him because it was not injured in Putnam County. But GenBioPro alleges that the Ban impermissibly constricts GenBioPro’s market for mifepristone in West Virginia, *including* within Putnam County. *See supra* pp. 5-6; Compl. ¶¶ 74-79. This economic injury is the “classic and paradigmatic form of injury in fact.” *Md. Shall Issue*, 971 F.3d at 210-11 (quoting *Air Evac*, 910 F.3d at 760). Sorsaia cites no law (at 3) for the proposition that GenBioPro must maintain a “corporate presence” within Putnam County to have suffered injury there — nor could he.⁴ “[C]onstriction of [GenBioPro’s] pool of

⁴ Sorsaia alleges (at 3 n.1) that a search on the West Virginia Secretary of State’s Office website does not reveal that GenBioPro registered to do business as a foreign corporation in West Virginia. His footnote is irrelevant and the Court should ignore it. First, the Court in ruling on a motion to dismiss takes the facts as found in the complaint, *Wei-ping Zeng v. Marshall Univ.*, 370 F. Supp. 3d 682, 686 (S.D.W. Va. 2019) (Chambers, J.), and does not consider unverified allegations made in the motion. Second, Sorsaia does not explain what relevance he believes attaches to GenBioPro’s registration status. Because GenBioPro’s medication is provided to patients through intermediaries, including healthcare providers and

potential customers” is sufficient. *Md. Shall Issue*, 971 F.3d at 212. This pool includes pharmacies in Putnam County. Compl. ¶ 78.

Second, Sorsaia incorrectly asserts (at 4) that GenBioPro’s injury must be “more traceable” to him than to any other prosecutor in West Virginia. In fact, an injury is “traceable if there is a causal connection between the injury and the conduct complained of by the plaintiff.” *Md. Shall Issue*, 971 F.3d at 212 (brackets and internal quotation marks omitted). A defendant’s conduct need not be the “last link in the causal chain,” or the “sole or even immediate cause of that injury.” *Id.* (brackets omitted). The fact that the injury “is at least partly caused by [the defendant’s] actions” suffices. *Sierra Club*, 899 F.3d at 285.

Sorsaia does not dispute that he is authorized to prosecute criminal violations of West Virginia’s Ban, but argues that (at 3) no prosecution is sufficiently “immediate” or “probable.” But “[i]t is not a leap of the imagination to predict what would occur if” any healthcare providers or pharmacies violated the law to prescribe or dispense GenBioPro’s product; Sorsaia has made clear that in those cases he would enforce the law. *W. Va. Citizens Def. League*, 2012 WL 4320983, at *9 & n.2; Compl. ¶ 24. Sorsaia’s unsupported statement (at 3) that GenBioPro does not complain about threatened prosecution in Putnam County contradicts the Complaint, which alleges that the Ban violates GenBioPro’s rights by, *inter alia*, subjecting providers otherwise eligible for certification under the REMS to criminal penalties, Compl. ¶ 96, including in Putnam County, *id.* ¶ 78.

pharmacies, GenBioPro is not required to register as a foreign corporation in West Virginia. This fact does not bear on the standing inquiry, and Sorsaia provides no support for his suggestion that it does.

Finally, Sorsaia incorrectly suggests (at 4-5) that because GenBioPro seeks “statewide” relief, it cannot sue a state official based in Putnam County. GenBioPro seeks relief against Sorsaia’s enforcement of the Criminal Abortion Ban. *See* Compl. at 32 (prayer for relief). Plaintiffs seeking statewide prospective relief are permitted to, and routinely do, name state officers at all levels as defendants. *See, e.g., Grabarczyk v. Stein*, 32 F.4th 301, 304 (4th Cir. 2022) (granting attorneys’ fees to prevailing plaintiff in *Ex parte Young* suit against attorney general and county district attorney, among others); *Nat’l Ass’n for Rational Sexual Offense L. v. Stein*, 2019 WL 3429120, at *1 (M.D.N.C. July 30, 2019) (denying motion to dismiss in *Ex parte Young* action against state attorney general and district attorneys); *Planned Parenthood*, 376 F.3d at 919-20 (holding attorney general and county prosecutor properly named as *Ex parte Young* defendants); *see Ex parte Young*, 209 U.S. 123 (1908). “The removal of even one obstacle to the exercise of one’s rights, even if other barriers remain, is sufficient to show redressability.” *Sierra Club*, 899 F.3d at 285.

II. GENBIOPRO’S COMPLAINT PLAUSIBLY ALLEGES VIABLE CAUSES OF ACTION

GenBioPro’s Complaint plausibly alleges causes of action under *Ex parte Young* and 42 U.S.C. § 1983. Compl. ¶¶ 21, 26, 93-101 (Count I), 102-111 (Count II); *id.* at 32 (prayer for relief). Each provides a viable basis for GenBioPro to obtain the prospective relief it seeks.

A. GenBioPro alleges causes of action under *Ex parte Young* and 42 U.S.C. § 1983

Ex parte Young provides a cause of action for plaintiffs “to petition a federal court to enjoin State officials . . . from engaging in future conduct that would violate the Constitution.” *Antrican v. Odom*, 290 F.3d 178, 184 (4th Cir. 2002); *see Ex parte Young*, 209 U.S. at 159-60. A plaintiff pleads an *Ex parte Young* action by alleging “an ongoing violation of federal law” and seeking “prospective” relief. *Franks v. Ross*, 313 F.3d 184, 197 (4th Cir. 2002) (quoting *Verizon*

Md. Inc. v. Pub. Serv. Comm’n, 535 U.S. 635, 645 (2002)). GenBioPro plausibly pleads such an action against Sorsaia by (1) alleging that he is the Prosecuting Attorney charged with enforcing the unconstitutional Ban in Putnam County and has stated his willingness to enforce this law, and (2) seeking prospective injunctive and declaratory relief from this Court. Compl. ¶ 24; *id.* at 32 (prayer for relief).

Federal law provides a cause of action under 42 U.S.C. § 1983 to any plaintiff that suffers “the deprivation of any rights, privileges, or immunities secured by the Constitution and laws [of the United States]” under color of state law. *Id.*; accord *Wirth v. Surles*, 562 F.2d 319, 322 (4th Cir. 1977) (“Where the violation of state law causes the deprivation of rights protected by the Constitution and statutes of the United States, a cause of action is stated under 42 U.S.C. § 1983.”). GenBioPro’s allegations that the Criminal Abortion Ban violates the Supremacy and Commerce Clauses of the Constitution state a cause of action under section 1983. *See* Compl. ¶¶ 93-101 (Count I), 102-111 (Count II); *see, e.g., Dennis v. Higgins*, 498 U.S. 439, 446 (1991) (“Petitioner contends that the Commerce Clause confers ‘rights, privileges, or immunities’ within the meaning of § 1983. We agree.”); *Waste Sys. Corp. v. Cnty. of Martin*, 985 F.2d 1381, 1389 (8th Cir. 1993) (affirming that plaintiffs could bring a section 1983 challenge for violation of the Commerce Clause). Sorsaia is a proper defendant for this action. *See Will v. Mich. Dep’t of State Police*, 491 U.S. 58, 71 n.10 (1989) (state officials may be sued for prospective relief under section 1983).

B. Sorsaia Enforces West Virginia Law In Putnam County And Has Threatened To Enforce The Criminal Abortion Ban; GenBioPro Seeks Prospective Relief To Enjoin Him From Doing So

Without addressing these causes of action,⁵ Sorsaia argues (at 5) that GenBioPro “failed to allege any viable cause of action” and that he cannot be held “liable for any misconduct toward” GenBioPro. Under *Ex parte Young*, however, Sorsaia is the proper defendant because he is a state official who has “some connection with the enforcement of the act” at issue. 209 U.S. at 157; *see McGee v. Cole*, 66 F. Supp. 3d 747, 753 n.1 (S.D.W. Va. 2014) (Chambers, J.) (“Under *Ex parte Young*, a plaintiff may challenge a state law as unconstitutional by suing a state official responsible for administering and enforcing that law.”). As the Prosecuting Attorney for Putnam County, Sorsaia has authority to enforce the Ban in his County. *See* W. Va. Code § 7-4-1(a). As courts in this Circuit have noted, *Ex parte Young* held that a state official whose “duties . . . included the right and the power to enforce the statutes of the state[] sufficiently connected him with the duty of enforcement to make him a proper party to an action challenging a state statute’s constitutionality.” *Does 1-5 v. Cooper*, 40 F. Supp. 3d 657, 673 (M.D.N.C. 2014).

Additionally, “[t]he requirement that the violation of federal law be ongoing is satisfied when a state officer’s enforcement of an allegedly unconstitutional state law is threatened, even if the threat is not yet imminent.” *Waste Mgmt. Holdings, Inc. v. Gilmore*, 252 F.3d 316, 330 (4th Cir. 2001); *see also Summit Med. Assocs., P.C. v. Pryor*, 180 F.3d 1326, 1339 (11th Cir. 1999) (holding *Ex parte Young* action proper when appellants noted their willingness “to prosecute violators of both statutes” at issue, even though they “ha[d] not yet initiated prosecution, nor ha[d] they specifically threatened Appellees with prosecution”). Sorsaia has the

⁵ By failing to engage with GenBioPro’s *Ex parte Young* and section 1983 claims, Sorsaia has forfeited arguments against them.

power to enforce the Ban, *see supra* pp. 9-10, and has threatened to enforce it, *see* Compl. ¶ 24 & n.7 (explaining that “[a]s prosecutors we have a clear obligation to enforce the laws of our state” concerning abortion). *Cf. Meredith v. Stein*, 355 F. Supp. 3d 355, 363 (E.D.N.C. 2018) (a “credible threat of prosecution” can exist, and make a pre-enforcement suit appropriate, “even when the government has not affirmatively stated its intention to prosecute”) (citing *Humanitarian L. Project*, 561 U.S. at 15).

GenBioPro also satisfies the second element of an *Ex parte Young* action: seeking prospective relief. An *Ex parte Young* plaintiff may seek only “prospective relief” in the form of an injunction or declaratory judgment. *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 105 (1984); *see Meredith*, 355 F. Supp. 3d at 364 (declaratory relief qualifies as prospective relief). That is what GenBioPro’s Complaint requests. Compl. at 32 (prayer for relief).

C. Sorsaia’s Remaining Arguments For Dismissal Under Rule 12(b)(6) Fail For Largely The Same Reasons That His Rule 12(b)(1) Arguments Fail

Sorsaia’s Rule 12(b)(6) arguments sound similar themes to his Rule 12(b)(1) argument: that he is not the proper defendant because the claims do not “specific[ally] reference” him (at 5), that he has “no legal authority or responsibility for defending” West Virginia’s laws against a constitutional challenge (at 5-6); that he has not “initiated or threatened any prosecutions to enforce” the Ban; and that the businesses GenBioPro would supply with mifepristone but for the Ban — Walgreens and CVS — “are not even named parties to this case” and may not suffer a “greater risk of . . . harm” in Putnam County than elsewhere in the State (at 6). These arguments do not contest the plausibility of GenBioPro’s claims. Instead, they reargue GenBioPro’s standing to sue Sorsaia and are unavailing for the reasons discussed *supra* pp. 4-15.

Contrary to Sorsaia’s argument (at 5-6), it is irrelevant that West Virginia does not require Sorsaia to defend the constitutionality of its laws. Sorsaia is a proper defendant because

GenBioPro's financial injury is fairly traceable to his conduct in enforcing West Virginia's criminal laws in Putnam County and would be redressed by a favorable ruling from this Court. *See supra* pp. 8-12. *Ex parte Young* plaintiffs regularly name defendants other than state attorneys general when challenging a law's constitutionality, as GenBioPro does. *See supra* pp. 15-16 (citing cases).

Equally lacking in legal support is Sorsaia's argument (at 6) that GenBioPro's "Complaint lacks the facial plausibility required" because GenBioPro did not seek a preliminary injunction. Sorsaia cites no case for the proposition that a preliminary injunction is a necessary element of GenBioPro's claims. "[T]he party who brings a suit is master to decide what law he will rely upon." *Fair v. Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1913) (Holmes, J.).⁶

To bring suit, GenBioPro need only plead the two elements of an *Ex parte Young* claim and allege enough facts "to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. It has.

CONCLUSION

For these reasons, the Court should deny Defendant Sorsaia's Motion to Dismiss.

⁶ Under Sorsaia's approach, defendants would get to nullify perfectly valid lawsuits on the theory that plaintiffs should have ascertained (somehow) an even more suitable defendant to sue for a declaration that a state law is unconstitutional and therefore unenforceable. He cites no case for that proposition.

Dated: March 7, 2023

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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

GENBIOPRO, INC.,

Plaintiff,

v.

**MARK A. SORSAIA, in his official capacity
as Prosecuting Attorney of Putnam County
AND PATRICK MORRISEY, in his official
capacity as Attorney General of West Virginia,
Defendants.**

**Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)**

CERTIFICATE OF SERVICE

I, the undersigned, counsel for Plaintiff, GenBioPro, Inc., do hereby certify that on March 7, 2023, I electronically filed and served the foregoing **PLAINTIFF'S OPPOSITION TO DEFENDANT MARK A. SORSAIA'S MOTION TO DISMISS** with the Clerk of the Court and all parties using the CM/ECF system.

Respectfully submitted,

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